

K112575

DEC 27 2011

2. 510(k) Summary

GEISTLICH PERIO-SYSTEM COMBI-PACK

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person: Daniel Kracov, Arnold & Porter, LLP
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Phone: (202)942-5120
Date Prepared: December 13, 2011

DEVICE NAME

Proprietary Name: Geistlich Perio-System Combi-Pack (containing one unit of Geistlich Bio-Oss Collagen® and one unit of Geistlich Bio-Gide® Perio)

Common/Usual Names: Natural Bone Grafting Material Plus Collagen Resorbable Bilayer Membrane for GTR/GBR

Classification Name: Bone grafting material, animal source (NPM)
Barrier, animal source, intraoral (NPL)

PREDICATE DEVICES

Bio-Oss Collagen® (K092428, K033815, K974399)
Bio-Gide® (K050446, K042197, K960724)

DEVICE DESCRIPTION

Geistlich Perio-System Combi-Pack is a convenience kit containing one unit of Geistlich Bio-Oss Collagen® and one unit of Geistlich Bio-Gide® Perio.

Geistlich Bio-Oss Collagen® (sold either as an individual unit or as one of the components of Geistlich Perio-System Combi-Pack) is a combination of purified spongiosa (cancellous) natural bone mineral granules and 10% collagen fibers in a block form and is sterilized by gamma irradiation.

Geistlich Bio-Gide® Perio (sold either as an individual unit or as one of the components of Geistlich Perio-System Combi-Pack) is a pure collagen membrane with a bilayer structure and smoothed dense (cell-occlusive) surface. The modified surface makes the membrane somewhat stiffer in the dry state, and this facilitates cutting the membrane for periodontal applications.

The porous surface (facing the bone) allows the ingrowth of bone forming cells, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the defect. The membrane is made of collagen without further cross-linking, and is sterilized by gamma irradiation. The size of the Geistlich Bio-Gide® Perio bilayer membrane to be provided in the Geistlich Perio-System Combi-Pack convenience kit and as individual units is 16 mm x 22 mm.

Preformed sterile templates are provided to simplify the cutting of the respective membrane shape. Four templates (uncoated Tyvek®) are packaged with Geistlich Bio-Gide® Perio to serve as an aid to assist the clinician in trimming the Geistlich Bio-Gide® Perio membrane to fit the defect, and are in varying shapes to fit the clinical need (e.g., rectangular, interproximal). The templates are packaged as an accessory product with Geistlich Bio-Gide® Perio.

INTENDED USE

Geistlich Bio-Gide® Perio is intended for the following uses:

- Augmentation around implants placed in immediate extraction sockets;
- Augmentation around implants placed in delayed extraction sockets;
- Localized ridge augmentation for later implantation;
- Alveolar ridge reconstruction for prosthetic treatment;
- Filling of bone defects after root resection, cystectomy, removal of retained teeth;
- Guided bone regeneration in dehiscence defects;
- Guided tissue regeneration procedures in periodontal defects.

Geistlich Bio-Oss Collagen® is intended for the following uses:

- Augmentation or reconstructive treatment of the alveolar ridge;

- Filling of periodontal defects;
- Filling of defects after root resection, apicoectomy, and cystectomy;
- Filling of extraction sockets to enhance preservation of the alveolar ridge;
- Elevation of the maxillary sinus floor;
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR);
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

The two products are being packaged together as a convenience kit for the ease of clinician use in periodontal regenerative procedures. In addition, Geistlich Bio-Gide® Perio will be packaged and sold as individual units.

TECHNOLOGICAL CHARACTERISTICS

Geistlich Bio-Oss Collagen® and Geistlich Bio-Gide® Perio, the two component devices of Geistlich Perio-System Combi-Pack, have the same technological characteristics (e.g., design, material) and intended use of their respective predicate devices, Bio-Oss Collagen® and Bio-Gide®.

PERFORMANCE DATA

A published nonclinical animal study provides histological evidence that Geistlich Bio-Gide® Perio, in combination with Geistlich Bio-Oss Collagen®, regenerates bone in 5 mm diameter rabbit femoral defects (1). Several published clinical studies demonstrate improvements in clinical attachment levels and probing pocket depths through 5-year follow-up versus the control (access flap surgery) (2,3,4). Histological evaluation of teeth in a case series demonstrated periodontal regeneration (5).

The results of these published studies demonstrate the substantial equivalence of Geistlich Bio-Gide® Perio and Geistlich Bio-Oss Collagen® to their respective predicate devices.

1. Lysiak-Drwal K, Dominiak M, Solski L, Zywicka B, Pielka S, Konopka T, Gerber H. Early histological evaluation of bone defect healing with and without guided

bone regeneration techniques: Experimental animal studies. Postepy Hig Med Dosw (online) 2008;62:282-288.

2. Sculean A, Berakdar M, Chiantella GC, Donos N, Arweiler NB, Brex M. Healing of intrabony defects following treatment with a bovine-derived xenograft and collagen membrane. A controlled study. J Clin Periodontol. 2003;30:73-80, 2003.
3. Sculean A, Chiantella GC, Windisch P, Arweiler NB, Brex M, Gera I. Healing of intra-bony defects following treatment with a composite bovine-derived xenograft (Bio-Oss Collagen) in combination with a collagen membrane (Bio-Gide Perio). J Clin Periodontol. 2005;32:720-724.
4. Sculean A, Schwarz F, Chiantella GC, Donos N, Arweiler NB, Brex M, Becker J. Five-year results of a prospective, randomized, controlled study evaluating treatment of intra-bony defects with a natural bone mineral and GTR. J Clin Periodontol. 2007;34:72-77.
5. Sculean A, Stavropoulos A, Windisch P, Keglevich T, Karring T, Gera I. Healing of human intrabony defects following regenerative periodontal therapy with a bovine-derived xenograft and guided tissue regeneration. Clin Oral Invest. 2004;8:70-74.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Geistlich Pharma AG
C/O Mr. Daniel A. Kracov
Arnold & Porter LLP
555 Twelfth Street, NW
Washington, D.C. 20004

DEC 27 2011

Re: K112575
Trade/Device Name: Geistlich Perio-System Combi-Pack
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM, NPL
Dated: December 20, 2011
Received: December 21, 2011

Dear Mr. Kracov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'A. Watson'.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112575

Device Name: Geistlich Perio-System Combi-Pack

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- Filling of defects after root resection, apicoectomy, and cystectomy;
- Filling of extraction sockets to enhance preservation of the alveolar ridge;
- Elevation of the maxillary sinus floor;
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR);
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Prescription Use X AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D)
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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